

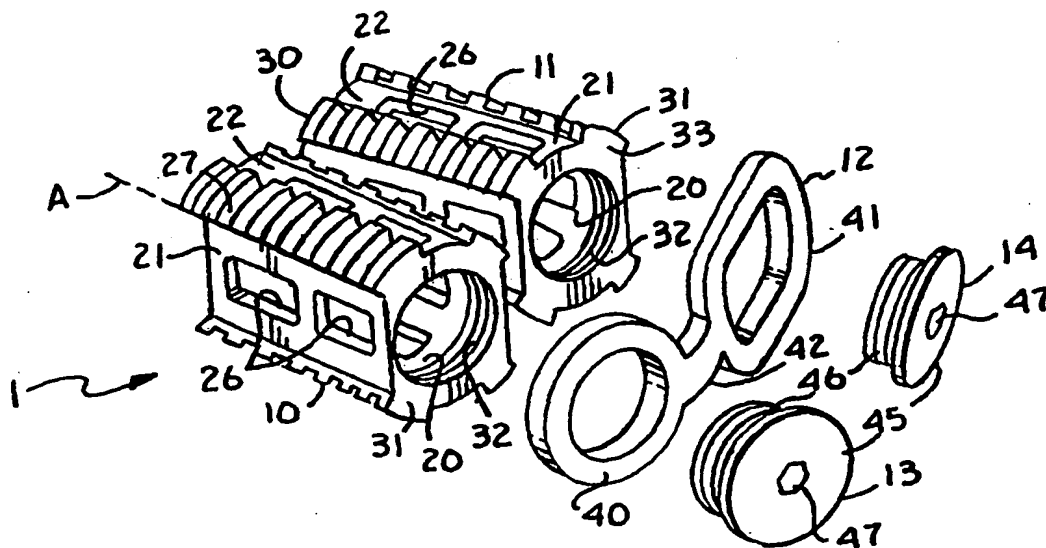


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(54) Title: SPINAL FUSION APPARATUS AND METHOD



## (57) Abstract

An apparatus (1) for stabilizing, promoting fusion between adjacent vertebrae includes at least a pair of implants (10, 11) to promote bone growth, and to fuse with vertebral bone. The implants (10, 11) are joined by a connector (42). Preferably the implants (10, 11) are inserted into receiving bores in a non-parallel configuration, and/or the connector (42) joins the implants so as to bias the implants to a non-parallel configuration. A pair of connection members (40, 41) also preferably secure the implants to each of the adjacent vertebrae. A method of using the apparatus (1) provides for stabilizing between vertebrae where the original cushioning disc has deteriorated or becomes damaged.

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## 1 SPINAL FUSION APPARATUS AND METHOD

3 Background of the Invention

5 The present application is directed to an apparatus and  
6 method of stabilizing the spine by placement of implants  
7 between effected vertebrae which result in fusion of the  
8 vertebrae. In particular, the present application is  
9 directed to an apparatus and method of improving the  
10 stabilization of the implants during the fusion process by  
11 linking the implants that are positioned between the same  
12 vertebrae together in pairs and also linking the implants to  
13 adjacent vertebrae. Still further the apparatus and method  
14 provides some pre-loading or twisting of the implants such  
15 that the axes of the implants are not parallel, so that the  
16 implants are further stabilized relative to their position  
17 between the vertebrae and more difficult to inadvertently  
18 dislodge.

19 Many millions of people in the United States alone  
20 suffer from some type of spinal injury or disease that  
21 effects the spine and especially the discs that are located  
22 between adjacent vertebrae of the spine. These discs are  
23 necessary to properly position and cushion the vertebrae  
24 during the movement. Degeneration, injury or other damage  
25 to the disc results in improper alignment of and dysfunction  
26 of the vertebrae which often also results in severe pain,

1 the inability to move correctly or to perform certain  
2 functions, paralysis and other physical problems which may  
3 leave the patient totally incapacitated. Approximately ten  
4 percent of the persons who have degeneration or herniation  
5 of discs are candidates for surgery to correct the problem.  
6 Many different systems have been developed to provide relief  
7 to persons having defective discs some of which have been  
8 effective and some of which have been relatively  
9 ineffective. One of the methods of correcting disc defects  
10 has been to properly position the adjacent vertebrae  
11 relative to each other and then fuse them together in the  
12 proper position or alignment.

13 Fusing often is best in situations where the discs  
14 between the adjacent vertebrae have been either damaged or  
15 diseased to such an extent that one or more of the discs no  
16 longer functions properly and cannot be preserved by simple  
17 procedures such as removal of herniated material and the  
18 like.

19 One particular type of fusion device which requires  
20 insertion of an implant having live bone between the  
21 vertebrae has grown in substantial popularity in recent  
22 years. In this type of implant, two such devices are often  
23 inserted in spaced relationship relative to one another  
24 between two adjacent vertebrae in the region normally  
25 occupied by the defective disc. In order to accomplish  
26 this, at least part of the disc is removed or the entire

1 disc is removed (discectomy) and the intervertebral implant  
2 devices, often referred to as cages, are inserted in  
3 receiving bores. Such implants have exterior walls which  
4 are fenestrated, porous or windowed so as to provide  
5 multiple openings therethrough. The interior of each of the  
6 implants is filled with live bone harvested from another  
7 part of the persons body, such as the hip and after  
8 implantation, the bone of the vertebrae grows into and joins  
9 with the live bone in the implants such that the two  
10 adjacent vertebrae and the implant bone grow into a single  
11 mass causing a fusion of the two vertebrae so as to hold  
12 them in a desired position. While this procedure reduces  
13 flexibility of the vertebrae, it significantly reduces pain  
14 and/or nerve damage due to collapse, missing or defective  
15 discs and, therefore, the benefits outweigh the lost  
16 flexibility. This is especially true where the patient would  
17 otherwise be immobile.

18 Applicant, as a spinal surgeon, has found that it is  
19 desirable to further stabilize the implants, especially  
20 during the period between implantation and the time when  
21 stabilizing fusion occurs. Consequently, applicant has  
22 developed an apparatus and method of joining a pair of  
23 implants that are located between two vertebrae in such a  
24 manner as to further stabilize the pair such that they are  
25 not as likely to become dislodged at some time before the  
26 fusion process is complete or afterward. In addition

1 applicant has found it is desirable to secure implants to  
2 vertebrae on opposite sides of the implant and to other  
3 implants so as to further improve the stability of those  
4 implants.

5 Finally, applicant has found that it is desirable to  
6 position the implants such that the central axis of the  
7 implants are not parallel to one another prior to joining  
8 such that it is more difficult to accidentally remove the  
9 implants from bores that receive the implants prior to  
10 completion of the fusion process. Yet further applicant has  
11 found it desirable to place a slight torque on the implants  
12 such that they are biased against the sides of the bore in  
13 opposite directions so as to yet further assist in  
14 maintaining the implants between the vertebrae during the  
15 fusion process.

#### 16 17 18 Summary of the Invention

19  
20 The present invention is directed to implants utilized  
21 to stabilize vertebrae wherein the pad or disc between  
22 adjacent vertebrae has deteriorated or been damaged and no  
23 longer properly spaces and cushions the vertebrae. Implants  
24 of the type of the present invention have been previously  
25 used to both separate and support adjacent vertebrae while  
26 functioning as a promoter for encouraging bone fusion to

1 occur between the vertebrae. The present invention further  
2 stabilizes such implants to allow the implants to form a  
3 quicker and stronger fusion platform and, very importantly,  
4 reduce the risk that the implants will become unseated and  
5 either require surgery to repair or that the implants will  
6 impinge on a nerve, blood vessel, or other structure and  
7 produce serious injury either directly or indirectly due to  
8 instability of the vertebrae supported by the implants.

9 In particular the apparatus of the invention includes a  
10 pair of implants shaped and sized to be received in a bore  
11 or alternatively to be driven by tapping between the  
12 vertebrae, each having an axis of insertion and each being  
13 placed between two adjacent vertebrae. The implants include  
14 a central chamber that receives bone for fusion or material  
15 to function as a matrix promoting bone growth and has a  
16 plurality of radially located apertures between the chamber  
17 and the exterior that allow bone from the vertebrae to grow  
18 into and fuse with the bone in the chamber. Alternatively,  
19 other types of implants may be used including carbon fiber,  
20 porous tantalum or any structure compatible with  
21 implantation in the human body and adapted to support bone  
22 growth so as to join adjacent vertebrae together through  
23 promotion of bone growth and fusion. The implants that are  
24 secured into bores preferably include an external rough  
25 thread that is sized and shaped to be received in a similar  
26 thread in the implant receiving bores to assist in securing

1 the implants in the implant receiving bores.

2 The implants are joined by a connector. In one  
3 embodiment the connector element is an elongate and  
4 generally rigid bar of rectangular cross-section that is  
5 received in recesses in the front of each implant and  
6 secured thereto by fasteners. Preferably, the connector is  
7 not aligned to be perpendicular to the central axis is  
8 slightly bowed at an angle preferably between about 2° to  
9 10°. This allows the implants to be biased relative to each  
10 other such that the implants are non-parallel after  
11 completion of the implantation. This urges the implants  
12 into the sidewalls of the implant receiving bores, which may  
13 also be non-parallel, and makes it more difficult for the  
14 implants to be unintentionally disturbed while in the  
15 implant receiving bores or pulled entirely from the bores.

16 In a second embodiment the connecting element is a  
17 relatively thin plate connecting the implants and also  
18 preferably designed to allow the implants to be aligned to  
19 be non-parallel. The plate also includes at least one  
20 elongate slot so that upon installation, a set screw can  
21 slide along the plate during tightening while effectively  
22 biasing the implants against the wall of the implant  
23 receiving bores.

24 In a third embodiment a connecting plate joins two tap-  
25 in type intervertebral implants. To gain additional  
26 stability a pair of L-shaped connecting plates are secured



1 to the implants near one end thereof and to the adjacent  
2 vertebrae. Also the implants between different vertebrae  
3 are joinable by a connecting strip.  
4

5 Objects and Advantages of the Invention

6  
7 Therefore, the objects of the present invention are: to  
8 provide a spinal stabilizing system having an apparatus  
9 including implants that are positioned in bores between  
10 vertebrae having a degenerated or damaged disc wherein the  
11 implants include live bone or are constructed of bone growth  
12 enhancing material for generating fusion between the  
13 vertebrae and wherein the implants are joined for greater  
14 stabilization during the fusion process; to provide such an  
15 apparatus that provides for proper spacing and alignment  
16 between the vertebrae thereby relieving pressure on nerves,  
17 restoring strength to the spinal column and correcting other  
18 problems associated with vertebrae misaligned due to disc  
19 failure or related damage; to provide such an apparatus  
20 including structure to further join implants to adjacent  
21 vertebrae above and below the implants and other implants so  
22 as to additionally improve stabilization of the implant  
23 during the fusion process; to provide such an apparatus  
24 wherein the implants are joined in such a manner that the  
25 axes thereof are nonparallel so as to substantially reduce  
26 the likelihood of accidental dislodgement of the implants

1 from the bores in which they are seated or their correct  
2 position between the vertebrae; to provide such an apparatus  
3 where the implants are biased against the interior walls of  
4 the bores so as to further reduce the likelihood of  
5 inadvertent removal of the implants from the bores during  
6 the fusion process; to provide a method that utilizes the  
7 implants in such a manner as to provide an extremely stable  
8 implant construction during the fusion process to reduce the  
9 likelihood of disturbance of the implants or of accidental  
10 removal of the implants from the bores and to speed the  
11 fusion process so as to quickly stabilize the patient's  
12 spine; and to provide such an apparatus and method which are  
13 relatively simple to use, economical to produce and utilize  
14 and that are especially well adapted for the intended usage  
15 thereof.

16 Other objects and advantages of this invention will  
17 become apparent from the following description taken in  
18 conjunction with the accompanying drawings wherein are set  
19 forth, by way of illustration and example, certain  
20 embodiments of this invention.

21 The drawings constitute a part of this specification  
22 and include exemplary embodiments of the present invention  
23 and illustrate various objects and features thereof.

24  
25  
26 Brief Description of the Drawings

1        Figure 1 is a fragmentary perspective view of a  
2 patient's spine showing implants in accordance with the  
3 present invention inserted in a region normally occupied by  
4 a disc between two vertebrae wherein the implants are joined  
5 to each other by a stabilizing structure or apparatus  
6 according to the present invention.

7        Figure 2 is a perspective view of the patients spine  
8 prior to insertion of the implants illustrating the  
9 insertion of a non-circular spacer between the vertebrae.

10       Figure 3 is a front view of the vertebrae of the  
11 patients spine showing the spacer in phantom lines as the  
12 spacer was inserted and showing the vertebrae in phantom  
13 lines at the time of first insertion of the spacer and also  
14 showing the spacer in solid lines as the spacer is rotated  
15 to space the vertebrae that are shown in solid lines, when  
16 spaced.

17       Figure 4 is a perspective view of the patients spine  
18 illustrating the pair of vertebrae in spaced relationship to  
19 one another and illustrating a bore being produced by use of  
20 a drill and drill guide.

21       Figure 5 is a fragmentary cross-sectional view of the  
22 spine illustrating an implant receiving bore being drilled,  
23 taken along line 5-5 of Fig. 4.

24       Figure 6 is a fragmentary cross-sectional view of the  
25 spine illustrating a top threading the implant receiving  
26 bore, taken along line 5-5 of Fig. 4.

1        Figure 7 is a front view of the patient's spine  
2        subsequent to the production of an implant receiving bore by  
3        the steps of Figs. 2 through 6.

4        Figure 8 is a front view of the patient's spine showing  
5        an implant positioned in the bore formed in steps of Figs. 2  
6        through 7.

7        Figure 9 is a schematic top plan view of a pair of  
8        implants prior to joining of the implants.

9        Figure 10 is a schematic top plan view of the pair of  
10       implants subsequent to joining of the implants.

11       Figure 11 is an exploded and enlarged perspective view  
12       of the implants and a connecting element prior to joining of  
13       the implants.

14       Figure 12 is a perspective view of a portion of a first  
15       modified implant system showing an implant, a rod for  
16       connecting the implants and a pair of links for connecting  
17       the implants to adjacent vertebrae.

18       Figure 13 is a fragmentary perspective view of the  
19       first modified implant system positioned in a patients spine  
20       between two vertebrae and inter-connecting the vertebrae to  
21       the system.

22       Figure 14 is a front elevational view of a second  
23       modified implant system showing two pairs of top-in implants  
24       with connectors and a strip joining the connectors.

25       Figure 15 is a side elevational view of the upper pair  
26       of implants of Fig. 14, taken along viewing line 15-15.

- 1        Figure 16 is a side elevational view of the lower pair
- 2        of implants of Fig. 14, taken along viewing line 16-16.
- 3

Detailed Description of the Invention

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

The reference numeral 1 generally represents a first embodiment of a spinal stabilization and fusion enhancing apparatus or system 1 in accordance with the present invention shown in Figures 1 and 8 through 11 and showing installation of the apparatus 1 in Figures 1 through 10 in the spine 2 of a patient.

The fusion enhancing apparatus 1 includes a pair of bone receiving cages or implants 10 and 11 that are joined to a connecting plate 12 by a pair of set screws 13 and 14.

The implants 10 and 11 are designed to be received in a circular bore, but have a somewhat rectangular cross-section with arcing at four opposite corners. Implants of the type illustrated are sold in the marketplace by Spine-Tech Inc. and other manufacturers of spinal fusion type implants. In

1 accordance with the invention pairs of implants of a wide  
2 range of shapes and constructed of a wide range of materials  
3 may be utilized in the invention, provided that the implants  
4 are positionable between adjacent vertebrae, that is,  
5 intervertebral implants; are compatible with use in the  
6 human body; promote, encourage or enhance bone growth into  
7 the implant or between the vertebrae and are connectible.

8 Each of implants 10 and 11 (best seen in Fig. 11) are  
9 elongate and have a central axis A. Each of the implants 10  
10 and 11 also are somewhat annular in shape having a central  
11 chamber 20, surrounded by a wall 21 having an outer surface  
12 22. The wall 22 is penetrated by a plurality of ports or  
13 windows 26 that are radially positioned and open into the  
14 central chamber 20. The outer surface 22 also includes  
15 partial threads 27 interspaced at opposite corners with the  
16 windows 26.

17 Each implant 10 and 11 has an enclosed rear end 30 and  
18 a front end 31. The front end 31 has a threaded bore 32  
19 that is generally aligned with the axis A and an outer  
20 generally planar surface 33. When installed, bone chips 35,  
21 normally harvested from another part of the body such as the  
22 hip, are inserted in the chamber 20 (see Fig. 8).

23 The plate 12 is relatively rigid, but has a slight  
24 amount of resiliency. The plate 12 has two spaced loops 40  
25 and 41 joined by a connector 42. The loops 40 and 41 are  
26 sized and shaped to generally sit on the front end surface

1 33 of each of the implants 10 and 11. One of the loops 40  
2 is circular and the other loop 41 is oblong. The general  
3 reason for the difference in shape is that the loop 40 is  
4 joined to an implant 10 or 11 first and, thereafter, the  
5 loop 41 to the opposite implant. The oblong nature of the  
6 loop 41 is necessary to allow for various spacing of the  
7 implants 10 and 11 and more importantly to allow the second  
8 of the set screws 13 or 14 to be started into the associated  
9 bore 32.

10 In particular, the plate 12 is bowed or bent from top  
11 to bottom across the connector 42. Normally, the angle of  
12 the bend will be in the range of 2° to 10° and, in the  
13 illustration the angle is about 7° and the bend can be seen  
14 in Figures 9 and 10.

15 The plate 12 is relatively rigid to hold the implants  
16 10 and 11 in a non-parallel relationship to each other as  
17 seen in Fig. 10 to make the implants 10 and 11 harder to  
18 disturb once implanted and to also provide a slight loading  
19 or bias to the implants 10 and 11 in some instances to  
20 further stabilize the apparatus 1.

21 The set screws 13 and 14 are sized and shaped to be  
22 received through the connector 42 loops 40 and 41  
23 respectively with a cap 45 abutting on and snugged against  
24 each respective loop 40 and 41. Each set screw includes a  
25 threaded surface 46 below the cap 45 that is operably  
26 received in a respective implant matingly threaded bore 32.



1 Each cap 45 also includes an opening 47 sized and shaped to  
2 receive a driving tool such as an allen wrench, screwdriver  
3 or the like (not shown).

4 In use, the patient's spine 2 is exposed and a pair of  
5 vertebrae 50 and 51 are exposed, normally by entry from the  
6 front. Although rear entry is possible, front entry is  
7 normally considered to be preferred to rear entry.

8 The vertebrae 50 and 51 to be stabilized and fused are  
9 first separated, since proper spacing has usually been  
10 compromised by a defective intervertebral disc or vertebrae  
11 damage. To space the vertebrae 50 and 51 a nonsymmetrical  
12 spacer having a rotating lug 61 is inserted between the  
13 vertebrae 50 and 51 on the left or right side (see Fig. 2).

14 The spacer 60 is then rotated (as seen in Fig. 3) and  
15 the vertebrae 50 and 51 are further spaced as illustrated by  
16 the difference between phantom lines (not spaced) and solid  
17 lines (spaced) in Fig. 3. Normally the vertebrae 50 and 51  
18 are spaced approximately to the limits of ligaments (not  
19 shown) holding the vertebrae 50 and 51 together.

20 A guide tool 63 is then positioned opposite the spacer  
21 60, as seen in Figs. 4 and 5. The guide tool 63 includes a  
22 tube 64 with pins 65 at one end to provide better gripping  
23 of the bone. The guide tool 63 aligns the location of a  
24 bore 68 to receive one of the implants 10 or 11. A drill  
25 bit 70 is inserted in the guide tool sleeve 64 and the bore  
26 68 is drilled. The drill bit 70 is then removed and a

1     threading tool 71 is inserted to form a coarse thread 72 on  
2     the interior of the bore 68 that mates with the thread 27 of  
3     implants 10 and 11.

4             The threading tool 71 is removed from the bore 68 and  
5     an implant 10 (see Fig. 8) is inserted. The spacer 60 is  
6     then removed and the drilling and threading procedure is  
7     repeated on the opposite side creating a second bore 74.  
8     The second implant 11 is then inserted in the second bore  
9     74, as seen in Fig. 1.

10            The connecting plate 12 is then attached to the  
11     implants 10 and 11 using the set screws 13 and 14. The  
12     implants 10 and 11 may originally be parallel as shown in  
13     Fig. 9 or the bores 68 and 74 may be drilled to be non-  
14     parallel. In either case, when the plate 12 is secured to  
15     the implants 10 and 11 (shown schematically in Fig. 10), the  
16     implants 10 and 11 are urged into a non-parallel alignment  
17     due to the angle of the bores 68 and 74, the loading of the  
18     plate 12 or both.

19            In particular, the set screw 13 is first placed to  
20     extend through the loop 40 into the bore 32 of implant 10  
21     and tightened. The second set screw 14 is likewise  
22     positioned with respect to implant 11. As the set screw 14  
23     is tightened the bend in the plate 12 biases the implants 11  
24     and 12 to a non-parallel alignment.

25            It is noted that the bores 68 and 74 may also be skewed  
26     (not in the same horizontal plane) to give the implants

1 greater gripping and purchase with respect to the vertebrae  
2 50 and 51, such that the implants 10 and 11 are more likely  
3 to resist forces that try to displace the implants 10 and 11  
4 during use.

5 The reference numeral 101 generally represents a  
6 modified stabilization apparatus or system that is  
7 illustrated in Figures 12 and 13. The system 101 which is  
8 seen installed in a spinal column 103 of a patient in  
9 association with and at least partly between a pair of  
10 vertebrae 104 and 105.

11 Individual elements of the stabilization system 101 are  
12 illustrated in Figure 12. The system 101 includes a pair of  
13 bone receiving and engaging cages or implants 109 and 110, a  
14 connecting element or bar 111 and a pair of connecting  
15 members 112 and 113.

16 Each of the implants 109 and 110 is cylindrical in  
17 shape having an annular wall 120. Each wall 120 is porous  
18 or heavily fenestrated and includes a plurality of pass  
19 through bores or apertures 121 that are generally radially  
20 aligned. The exterior of each of the walls 120 also  
21 includes a rough helical thread 122 that is aligned with a  
22 central axis of each respective implant 109 and 110 and  
23 which is designed to help secure each respective implant 109  
24 and 110 in a desired position thereof.

25 Each of the implants 109 and 110 includes a rear end  
26 124 for closing the rear end and has a front end 125 that

1 opens into an interior bore 126. An interior chamber 127 is  
2 thus formed between the annular wall 120 and the end cap 125  
3 that is not entirely enclosed as it opens outwardly through  
4 the various apertures 121.

5 The chamber 127 receives bone fragments 128 that are  
6 harvested from another part of the patient's body, such as  
7 the patient's hip. The front end 125 of each implant 109  
8 and 110 includes a rectangularly shaped recess sized and  
9 shaped to receive the connecting element, plate or bar 111.  
10 The recess 131 has a partial rear wall surface 132. The bar  
11 111 is not linear but has a bend or curve in the range of  $2^{\circ}$   
12 to  $10^{\circ}$ , preferably about  $5^{\circ}$ . This same feature may be  
13 created by a continuous curve or arc located between the  
14 implants 10 and 11. In this manner, when the connecting bar  
15 111 is placed in the recess 131 and abuts against the  
16 surface 132, the two implants 109 and 110 are urged to align  
17 in a slightly nonparallel relationship to one another,  
18 preferably so as to toe in or converge at the rear ends 124  
19 of the implants 109 and 110 opposite the bar 111.

20 It is foreseen that the axial deviation of the two  
21 implants 109 and 110 could also be spread further apart in  
22 the rear thereof as opposed to where the implants 109 and  
23 110 join the bar 111, that is diverge or toeout. On the  
24 other hand, the implants 109 and 110 may be aligned to also  
25 be skewed relative to one another and/or divergent or  
26 convergent.

1       The connecting bar 111 is bent on one outer wing 135  
2       thereof to conform to the curvature of the vertebrae 104 and  
3       105, as shown in Fig. 12. The wing 135 extends outwardly  
4       further than the opposite side of the bar 111 and is  
5       normally located on the left hand side of the patient. The  
6       wing 135 is so located, as surgeons normally enter from the  
7       front, but on the left side, so that the patient left hand  
8       location allows the surgeon better access.

9       Located in the wing 135 is a threaded bore 136 that  
10      receives a mating screw 137. The screw 137 is also received  
11      through one of a series of apertures 139 and 140 in each of  
12      the connecting members 112 and 113.

13      The connecting member 112 and 113 are L-shaped and each  
14      have a second set of threaded apertures 142 and 143 spaced  
15      from the wing 135 and positioned opposite the bones 104 and  
16      105 respectfully as shown in Figure 13. The bone screws 145  
17      and 146 are of the type having a thread 147 on the body for  
18      taping into bone and a second thread 148 on the head that is  
19      mated with the bores 142 and 143 respectfully.

20      The modified apparatus 101 is installed and functions  
21      in a similar manner to the apparatus 1 of the previous  
22      embodiment with the principal exception that the connecting  
23      members 112 and 113 are secured to the adjacent vertebrae  
24      104 and 105 so as to secure the apparatus 101 directly to  
25      the vertebrae 104 and 105.

26      Illustrated in Figures 14, 15 and 16 is a second

1 modified embodiment of a spinal stabilization apparatus in  
2 accordance with the invention, generally identified by the  
3 reference numeral 201 and used in conjunction with a spine  
4 202.

5 The apparatus 201 includes a first pair of implants 205  
6 and 206 joined by a first connecting member 207 and a second  
7 pair of implants 208 and 209 joined by a second connecting  
8 member 210. The implants 205, 206, 208 and 209 are similar  
9 to the implants of the previous embodiments in that each  
10 contains bone and has windows 212 or similar openings  
11 extending between an interior chamber holding the bone and  
12 an exterior.

13 The implants 205, 206, 208 and 209 are different in  
14 comparison to those of the previous embodiment in the shape  
15 and method of implantation thereof. The implants 205, 206,  
16 208 and 209 illustrate implant types that are placed between  
17 bones 220, 221 and 222 by striking or pushing, sometimes  
18 referred to as tap-in type herein, as opposed to being  
19 secured by screwing into previously formed bores.  
20 Consequently, the implants 205, 206, 208 and 209 have a  
21 rectangular cross section as opposed to circular or near  
22 circular cross section.

23 The implants 205, 206, 208 and 209 illustrate several  
24 different types. In particular the implants 205 and 206 are  
25 each generally rectangular when viewed from the side (see  
26 Fig. 15), but have different heights with implant 205 being

1 larger than implant 206. The implants 205 and 206 are used  
2 to support opposite sides of a bone 221 that has  
3 deteriorated or been damaged on the side requiring the  
4 larger implant 205 to level the opposite sides of the bone  
5 221.

6 The implants 208 and 209 have a trapezoidal  
7 configuration when viewed from the side (see Fig. 16) to  
8 operably space the front of the bones 222 and 223 more than  
9 the rear thereof.

10 The connector plates 207 and 210 are similar to the  
11 connector plate 12 of the first embodiment and join the  
12 implants 205 and 206 as well as the implants 208 and 209  
13 respectively with the one difference being that the plates  
14 207 and 210 each include a centrally located threaded bore  
15 230 that receives a threaded screw 231. Each of the  
16 connector plates 207 and 210 are joined to respective  
17 implants 205, 206, 208 and 209 by set screws 238.

18 An elongate strip 241 operably extends vertically along  
19 the front of the spine 202 and joins the connecting plates  
20 207 and 210. The strip 241 has a series of oval shaped  
21 apertures 244 that receive screws 231 so as to secure the  
22 strip 241 to each plate 207 and 210 and so as to further  
23 stabilize the apparatus 201 and spine 202.

24 The apparatus 201 is installed in a somewhat different  
25 manner than that of the previous embodiments. Instead of  
26 forming bores to receive the implants, any pad between bones

1 221, 222 and 223 is removed and the implants 205, 206, 208  
2 and 209 are driven into place by tapping or the like. The  
3 connecting plates 207 and 210 are then joined to respective  
4 implants 205, 206, 208 and 209 by set screws 238, as in the  
5 previous embodiments, with the plates 207 and 210 bent to a  
6 selected angle. The strip 241 is then joined to each  
7 connecting plate 207 and 210 by screws 231.

8 While the implants have mainly been described as cages  
9 for receiving bone to enhance bone growth into the cages and  
10 to fuse the vertebrae, it is foreseen that other types of  
11 implants may be used for this purpose. For example, carbon  
12 fiber implants, implants of porous tantalum and other  
13 structures of stainless steel, tungsten and other body  
14 friendly materials, either coated with bone growth enhancing  
15 medium or simply porous so as to support and encourage bone  
16 growth into and through the implants, may be utilized in  
17 accordance with the invention.

18 It is to be understood that while certain forms of the  
19 present invention have been illustrated and described  
20 herein, it is not to be limited to the specific forms or  
21 arrangement of parts described and shown.

22



C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. An apparatus for stabilizing between adjacent vertebrae of a spine by promotion of bone fusion between the adjacent vertebrae; said apparatus comprising:

- a) a pair of implants adapted to be received between adjacent vertebrae; each of said implants adapted to promote bone growth between the adjacent vertebrae;
- b) a connector joined to each of said implants; and
- c) fasteners securing said connector to each of said implants.

2. The apparatus according to Claim 1 wherein:

- a) said connector is a substantially rigid elongate bar.

3. The apparatus according to Claim 2 wherein:

- a) each of said implants has a recess located at said front end thereof; said bar being received in both of said recesses.

4. The apparatus according to Claim 3 wherein:
  - a) said bar is bent at an angle between  $2^{\circ}$  and  $10^{\circ}$ , such that when said bar is received in said recess, said implants are biased so that the central axes thereof are nonparallel.
5. The apparatus according to Claim 1 wherein:
  - a) said connector is a plate operably joined to the front end of each of said implants.
6. The apparatus according to Claim 5 wherein:
  - a) said plate is bent intermedially and is secured to said implants such that said implants are biased in such a manner that central axes associated with said implants are nonparallel when assembled.
7. The apparatus according to Claim 1 wherein:
  - a) each implant has a front end that has a pass through bore that is threaded; and
  - b) said fasteners comprise set screws operably joining said connector to said implants and being received in said threaded bore.

8. The apparatus according to Claim 1 including:
  - a) a vertebral connecting member; said connecting member being connected at a first portion location therealong to said implants and having a second spaced portion whereat said connecting member is adapted to be secured to one of the two adjacent vertebrae.
9. The apparatus according to Claim 8 wherein:
  - a) said connecting member is a first member; and including
  - b) a second connecting member operably secured to said implants and adapted to be secured to a second of the two adjacent vertebrae.
10. The apparatus according to Claim 9 wherein:
  - a) said first and second members are L-shaped and include apertures therealong to receive a series of bone screws to secure said members to said vertebrae.

11. An apparatus for stabilizing intervertebrally by promotion of bone fusion between two adjacent vertebrae of a spine; said apparatus comprising:

- a) a pair of implants adapted to be received between the adjacent vertebrae; each of said implants having an interior chamber for receiving bone fragments; and each of said implants having a plurality of radially positioned and wall penetrating apertures adapted to allow bone fragments in said bores to join and fuse with bone in the adjacent vertebrae;
- b) a connecting member operably joined to each of said implants;
- c) fasteners operably securing said connecting member to each of said implants.

12. A method of stabilizing and promoting bone fusion between two adjacent vertebrae comprising the steps of:

- a) selecting a pair of implants with each implant adapted to promote bone growth;
- b) forming a pair of implant receiving bores between the two adjacent vertebrae

- with each of the implant receiving bores sized to snugly receive a respective one of said implants;
- c) placing said implants in respective bores; and
  - d) joining a front end of each implant with a connector.
13. The method according to Claim 12 including the step of:
- a) prior to the step of forming said implant receiving bores, biasing apart said two adjacent vertebrae to the extent allowed by connecting ligaments.
14. The method according to Claim 13 wherein said biasing is performed by:
- a) inserting a non-circular plug between said vertebrae in a first alignment and then rotating said plug to space said vertebrae.
15. The method according to Claim 12 including:
- a) forming said implant receiving bores such that the central axes thereof are non-parallel.

16. The method according to Claim 15 wherein:
- a) said implant receiving bores diverge from front to rear.
17. The method according to Claim 12 including the step of:
- a) joining said implants to said connector in such a manner that central axes of each of said implants is in a non-parallel configuration relative to each other and held in such configuration by said connector.
18. The method according to Claim 12 including the step of:
- a) selecting a connecting member and securing said member to said implants and to one of said adjacent vertebrae by a fastener.

19. The method according to Claim 18 wherein:

- a) said member is a first member and including the step of selecting a second member and then securing said second member to said implants and to the second of said adjacent vertebrae.

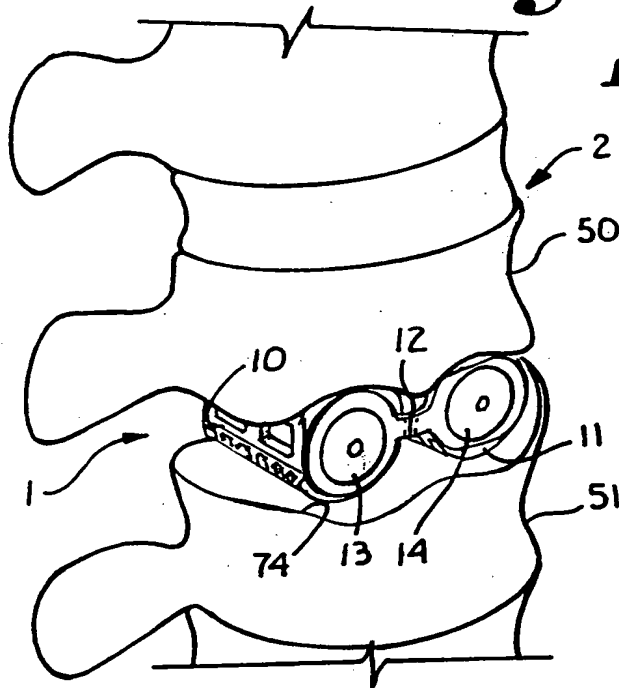
20. In an apparatus for promoting fusion between adjacent vertebrae including a pair of intervertebral implants; the improvement comprising:

- a) joining said implants with a connecting member.

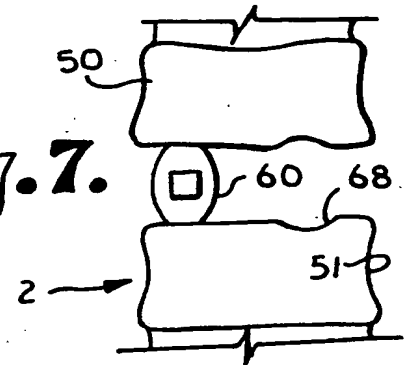
21. The apparatus according to Claim 20 wherein:

- a) said connecting member is bent such that said implants are urged to a non parallel alignment relative to each other.

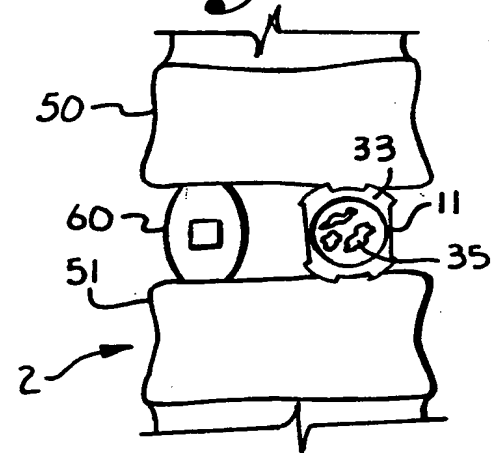
**Fig. 1.**



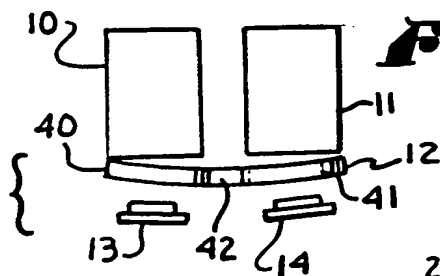
**Fig. 7.**



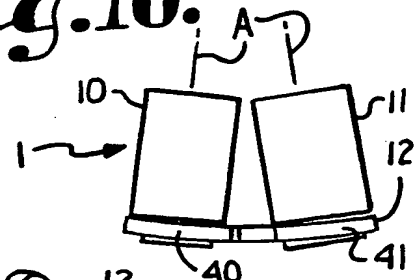
**Fig. 8.**



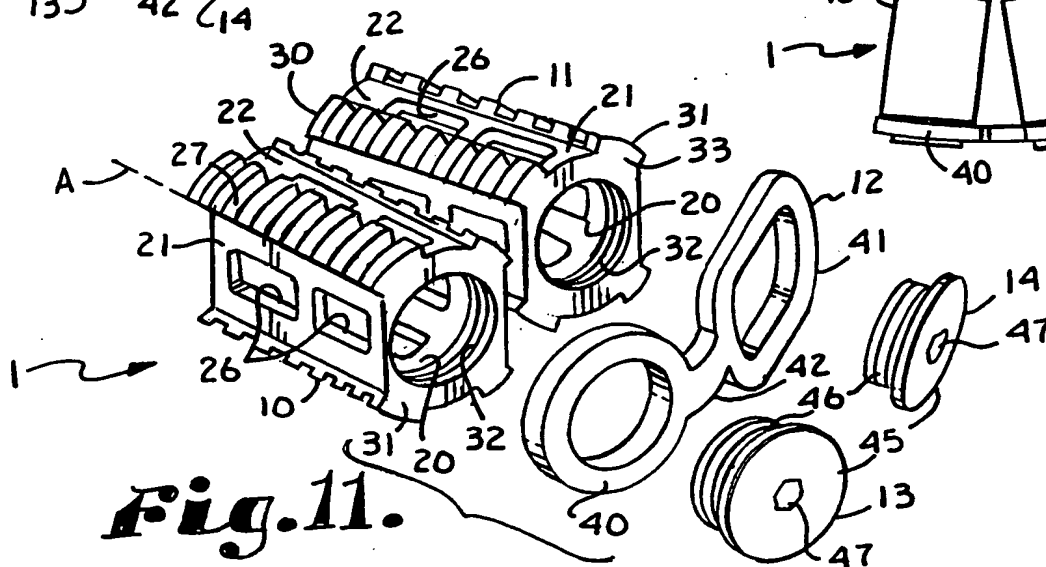
**Fig. 9.**



**Fig. 10.**

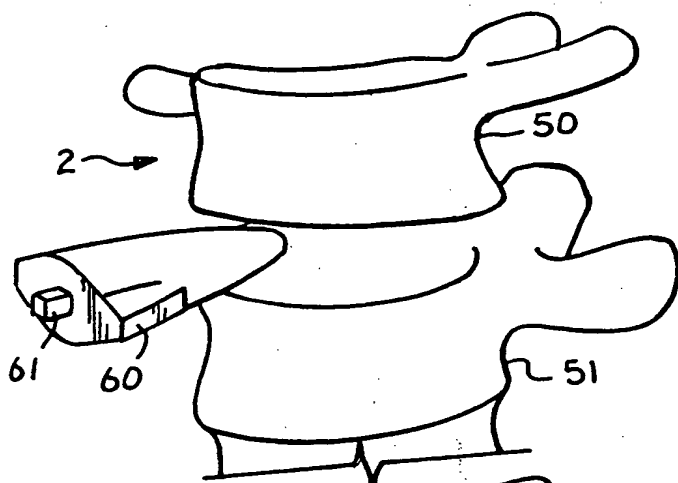


**Fig. 11.**

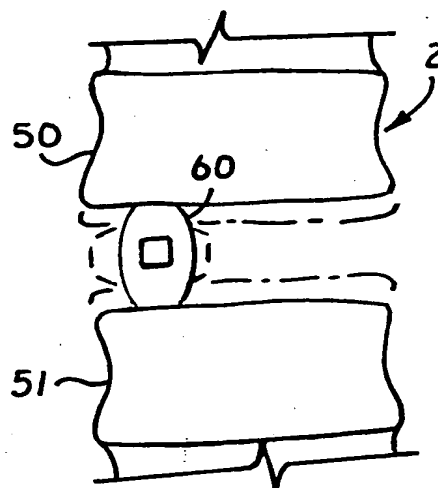




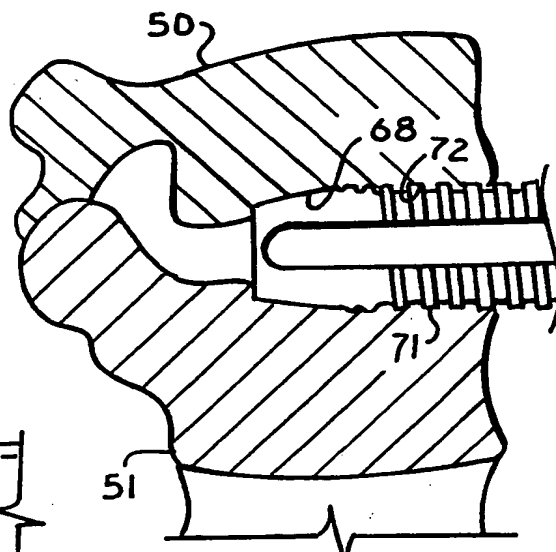
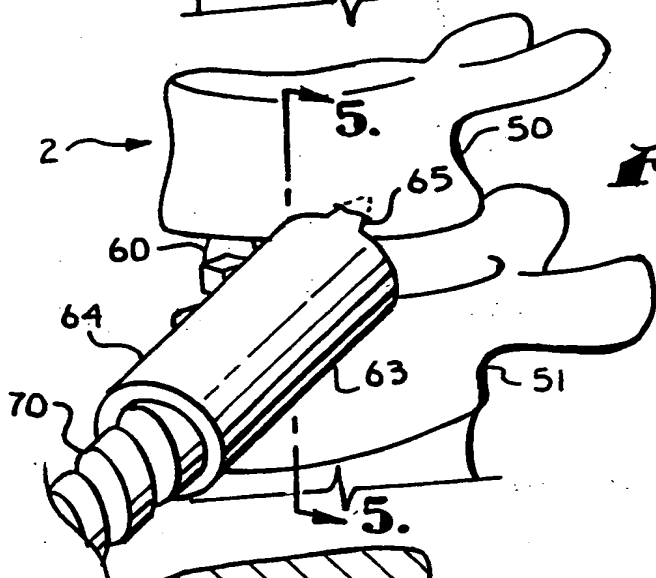
**Fig. 2.**



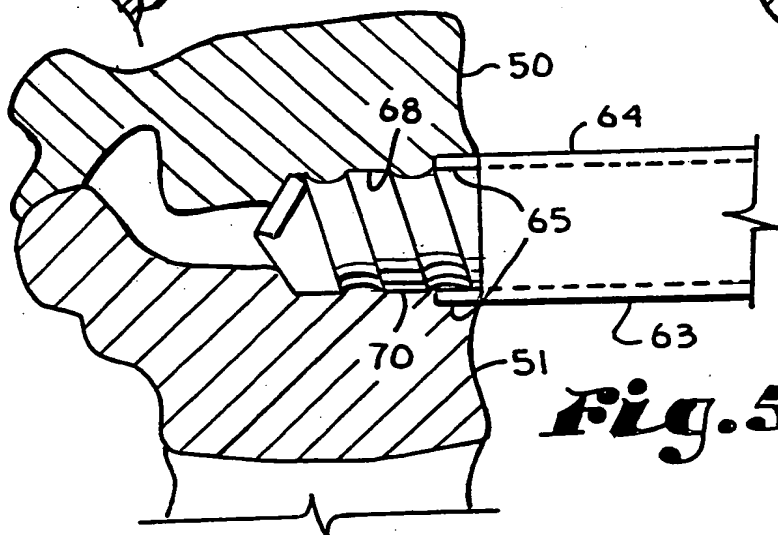
**Fig. 3.**



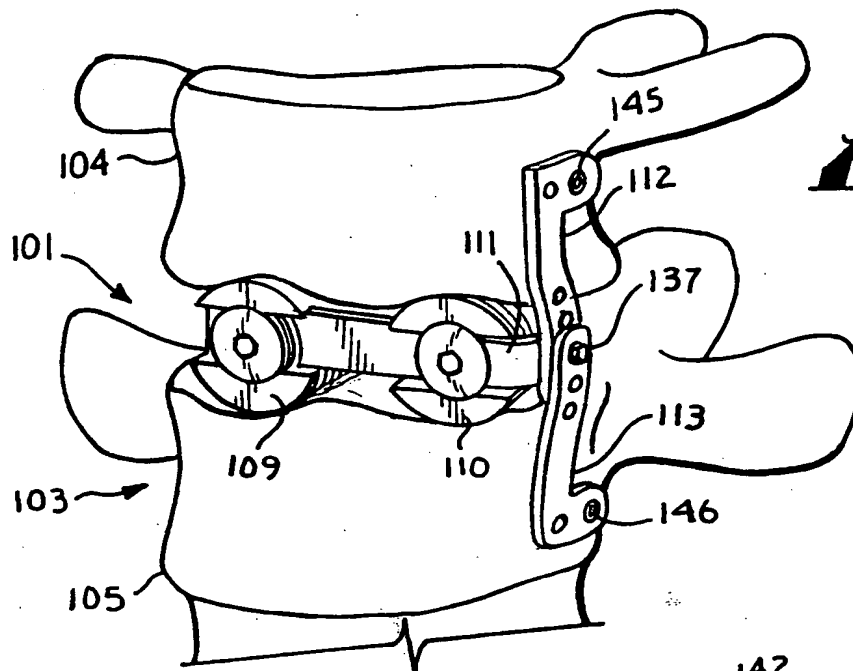
**Fig. 4.**



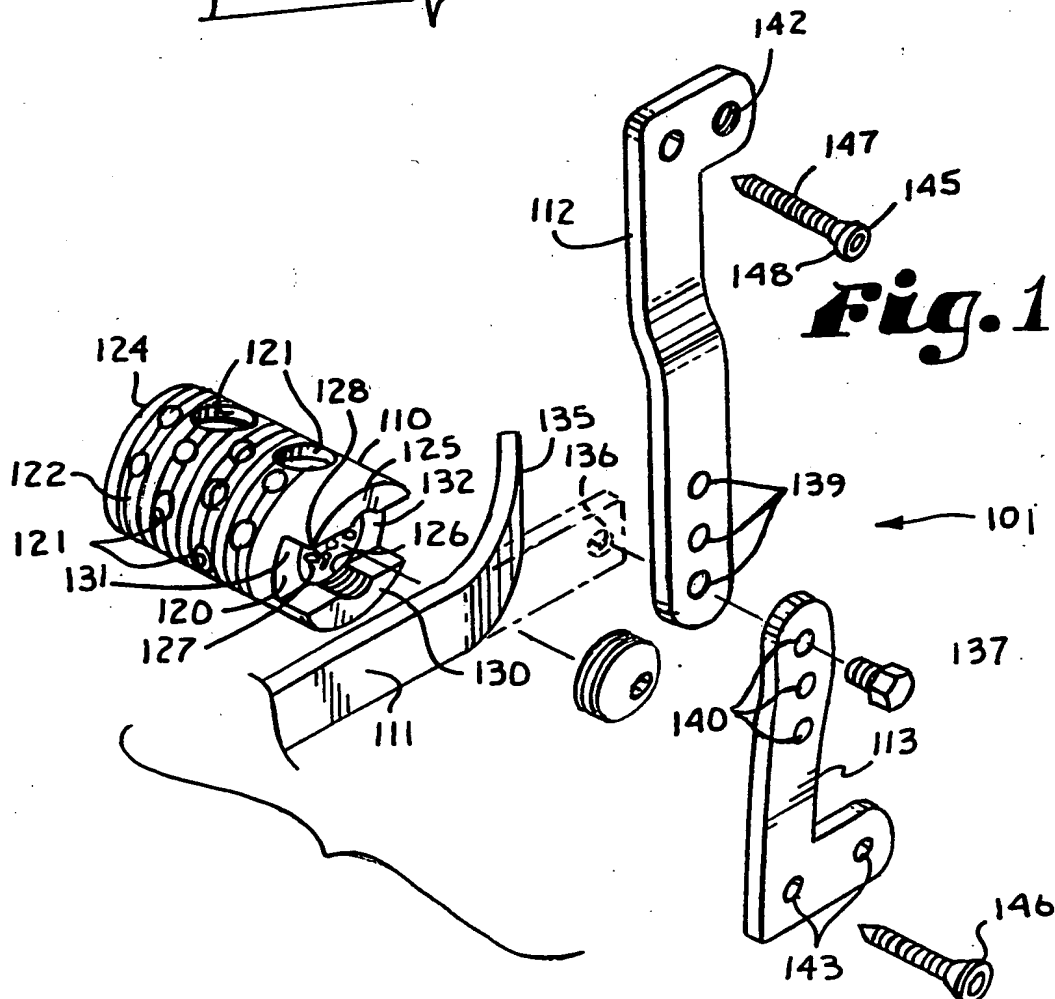
**Fig. 6.**



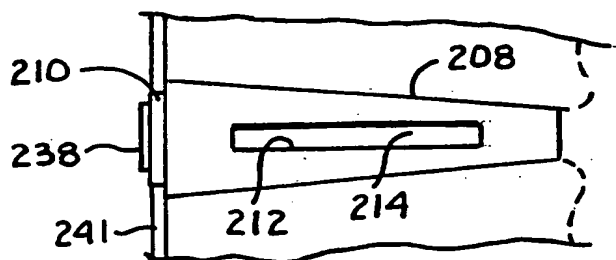
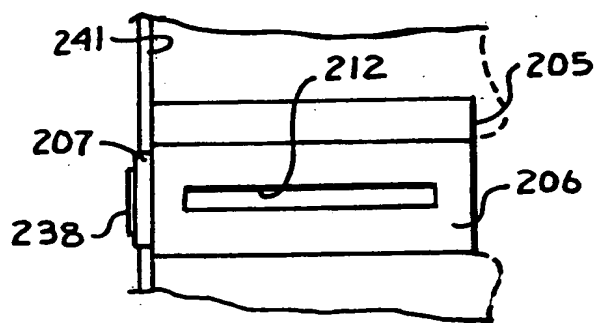
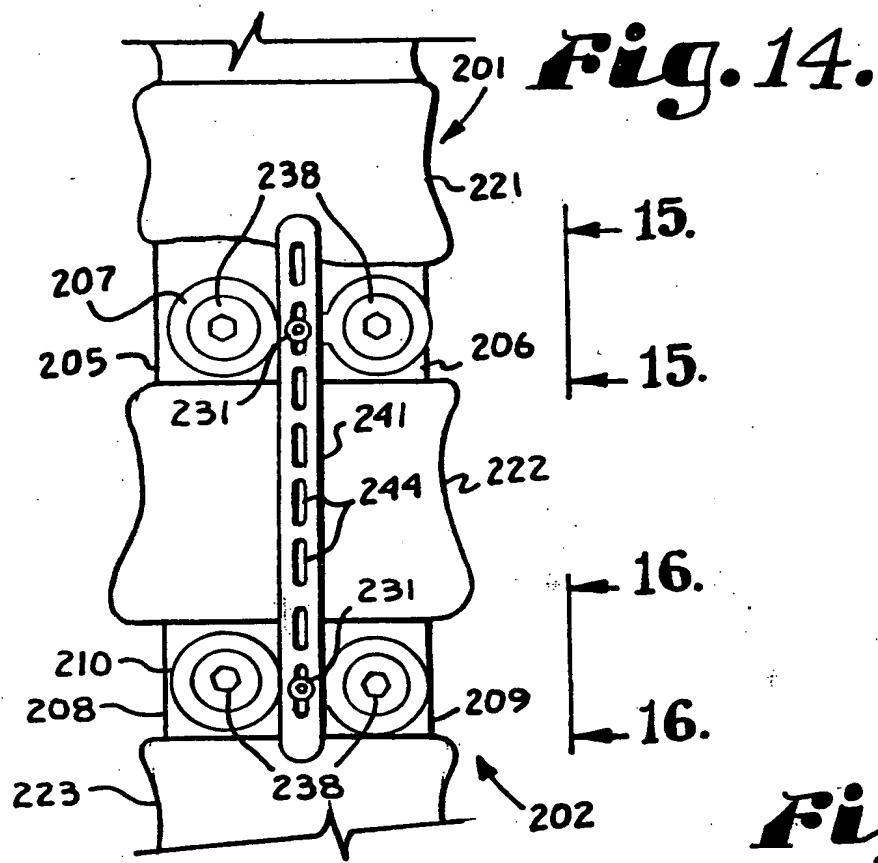
**Fig. 5.**



**Fig. 13.**



**Fig. 12.**



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/15714

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/56

US CL :606/61

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 60, 72, 73; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,489,308 A (KUSLICH et al.) 06 February 1996, Figs. 1, 26, and 28.	1-3, 5, 7, 11-14
X	US 5,055,104 A (RAY) 08 October 1992, Fig. 7.	1-3, 7, 11-14
X	US 5,683,391 A (BOYD) 04 November 1997, Fig. 3.	1-4, 7, 11-13, 15-21
Y		5, 6, 14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 AUGUST 1999

Date of mailing of the international search report

21 OCT. 1999

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